REMARKS

With this response, claims 32-48 are pending. Claims 32 - 37 have been amended without prejudice or disclaimer. Claims 38 - 48 have been newly added. Support for the foregoing amendment can be found throughout the specification and the claims as originally filed, for example, in the Substitute Specification at page 10, lines 21 - 23; page 60, line 1 - page 63, line 2; page 38, line 10 - page 41, line 18; page 56, lines 2-11; page 58, line 7 - page 59, line 5; and Table 14.

I. Rejection under 35 U.S.C. § 112, First Paragraph, Scope of Enablement

In rejecting claims 32-37[1] under 35 U.S.C. §112, first paragraph, the Examiner alleges that the specification "does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims." *Office Action* at page 4. The Examiner goes on to assert that the specification, "while being enabling for a method of increasing bone mass comprising administering a pharmaceutical preparation comprising the OCIF protein of SEQ ID NO:5 to increase bone mass, does not reasonably provide enablement for improving decreased bone mass by an OCIF protein encompassing its variants or fragments." *Id.* Applicants respectfully disagree.

Applicants submit that the claimed invention is enabled. That is, given the instant disclosure, Applicants respectfully assert that one of ordinary skill in the art would have the ability to practice the claimed invention without undue experimentation. A number of facts support this assertion.

For one, the Examiner acknowledges that the specification is enabled for a method of increasing bone mass comprising administering a pharmaceutical preparation comprising the OCIF protein of SEQ ID NO:5. *Id.* Consistent with the specification, the Examiner also notes that the OCIF protein of SEQ ID NO:5 is encoded by SEQ ID NO:6. *Office Action* at pages 5 and 9. That is, the OCIF protein encoded by SEQ ID NO:6 and the OCIF protein of SEQ ID NO:5 share 100% amino acid sequence identity. Since the Examiner notes that the OCIF protein of

[1] Claims 32-37 are all independent claims.

SEQ ID NO:5 is enabled, it would necessarily follow that a method of increasing bone mass by administering an OCIF protein encoded by SEQ ID NO:6 is also enabled. Specification at page 25, lines 13-15.

As the Federal Circuit noted in *In Re Wallach*, it is "a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it." 378 F.3d 1330, 1334 (Fed. Cir. 2004). Because one of ordinary skill in the art would have the ability to switch "back and forth" between an amino acid sequence and the nucleotide molecules encoding it, claims encompassing SEQ ID NO:6 must also be enabled.

The Examiner asserts that the phrase "an OCIF protein encoded by SEQ ID NO:6" allegedly encompasses "any OCIF protein, variant, or fragment." *Office Action* at page 4. Applicants disagree and respectfully submit that the Examiner has not provided any scientific or legal basis in support of this assertion. Moreover, Applicants respectfully assert that the Examiner is applying the wrong standard in interpreting the scope of the claims.

As set forth in MPEP § 2164.08, "when claims are directed to any purified and isolated DNA sequence encoding a specifically named protein where the protein has a specifically identified sequence, a rejection of the claims as broader than the enabling disclosure is generally not appropriate because one skilled in the art could readily determine any one of the claimed embodiments." That is, where claims are drawn to a purified and isolated DNA sequence encoding a specific protein, it is improper to reject the claims as being overly broad. Because certain claims are drawn to an OCIF protein encoded by a specific sequence, SEQ ID NO:6, Applicants respectfully submit that at least those claims were improperly rejected.

Moreover, Applicants respectfully submit that the Examiner erred with respect to the other claims. One of ordinary skill in the art would also recognize that the specification is enabled for improving decreased bone mass in humans. The Examiner seemingly acknowledges this by noting that "the specification further suggests the use of OCIF protein in pharmaceutical preparations for improving decreased bone mass in diseases, for example osteoporosis." *Office Action* at page 5. This is also confirmed by the specification, for example, by at least page 2, lines 1-3; page 10, lines 18-20; page 32, lines 7-10; Example 16; and Tables 4-8. Thus, in light

of the disclosure, methods drawn to improving decreased bone mass satisfy 35 U.S.C. § 112, first paragraph.

Applicants have provided considerable direction and guidance, and have presented working examples such that it is within the level of ordinary skill in the art to practice the invention without undue experimentation. In contrast, the Examiner has not provided specific or sufficient evidence to cast doubt on the guidance provided in the specification. Rather, the Examiner has provided generalizations regarding a lack of predictability in the art and the need for some experimentation.

Accordingly, for at least these reasons, it is submitted that the claims are sufficiently enabled under 35 U.S.C. § 112, first paragraph, and withdrawal of this rejection is respectfully requested.

II. Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 32-37 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *Office Action* at pages 8-11. In support of this rejection, the Examiner alleges that "the specification has not shown a relationship between structure, function, or properties of the claimed genus of polypeptides." *Office Action* at page 10. The Examiner goes on to state that "the brief description in the specification of one OCIF polypeptide (SEQ ID NO: 5) is not adequate written description of an entire genus of functionally equivalent polypeptides which incorporate all fragments, and variants of OCIF." *Id.* Applicants respectfully disagree.

The standard for determining whether a claim drawn to a genus meets the written description requirement is clear. "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice . . . , reduction to drawings . . . , or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or

by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." *See Regents of the University of California v. Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1406; M.P.E.P § 2163(II)(3)(a)(ii) (emphasis added). A "representative number of species" means that the species which are adequately described are representative of the entire genus. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. *Id.* Applicants have met this burden.

As set forth in *Regents of the University of California v. Eli Lilly,* "an adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention. 119 F.3d at 1568, 43 USPQ2d at 1404. This is exactly what Applicants have provided.

First, the chemical sequence listing for SEQ ID NO:6 is provided in the specification. Sequence listing at pages 6-7. This alone indicates that the Applicants were in possession of the claimed invention at the time of filing. Second, the specification describes the functional and physical properties of OCIF proteins encoded by SEQ ID NO:6. Specification at page 10, lines 12-17 and Figure 15. For example, the specification details the *in vivo* effect of OCIF on increasing the mechanical strength of bones in rats. *Id.* The specification also discloses the use of OCIF in improving decreased bone mass and increasing bone density. Specification at page 10, lines 18-20.

Moreover, the Examiner acknowledges that the OCIF polypeptide comprising the amino acid sequence of SEQ ID NO:5 satisfies the written description requirement. *Office Action* at page 11. The Examiner also confirms that the OCIF protein of SEQ ID No: 5 is encoded by SEQ ID NO:6, and that it has a role in bone absorption. *Office Action* at page 9. Because it is "a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it," Applicants respectfully submit that the claims would satisfy the written description requirement under 35 U.S.C. §112, first paragraph. *In Re Wallach* 378 F.3d 1330, 1334 (Fed. Cir. 2004). For example, the Examiner states that OCIF comprising the amino acid sequence of SEQ ID NO:5 satisfies the written description

requirement, it would necessarily be the case that a protein encoded by SEQ ID NO:6 (and sharing 100% sequence identity to the OCIF protein of SEQ ID NO:5) would also satisfy the written description requirement (for example, *see* claims 32-34).

Applicants respectfully submit that one skilled in the art would readily appreciate that Applicants, at the time of the filing of the present application, were in possession of the claimed invention and, therefore, have met the written description requirement. As such, it is submitted that the claims comply with 35 U.S.C. §112, first paragraph, and withdrawal of this rejection is respectfully requested.

III. Rejection under 35 U.S.C. § 112, Second Paragraph

The Examiner asserts that claims 32, 33, 35, and 36 are indefinite for allegedly failing to point out and distinctly claim the subject matter which applicant regards as the invention. *Office Action* at page 12. Applicants respectfully disagree.

The Examiner contends that, because the terms "improving," "improvement," and "decreased bone mass" are allegedly relative terms, they render the claims indefinite. *Id.* The Examiner further asserts that "the term decreased bone mass requires a point of reference and none is given" and "the term improving is vague because it requires a reference of an objective." *Id.* Applicants respectfully submit this rejection lacks any legal basis.

Applicants submit that the scope of the subject matter claimed is clear. Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. § 112, second paragraph. *See* MPEP § 2173.04. In context, the terms "improvement" or "improving" include increasing bone mass, maintaining bone mass, or reducing decrease in bone mass. Thus, all of these are within the scope of the claimed invention. Therefore, the rejection is improper and should be withdrawn.

Moreover, MPEP § 2173.02 states that the Examiner "should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though

the claim language is not as precise as the examiner might desire." In making this determination, MPEP § 2173.02 goes on to clarify that definiteness of claim language must be analyzed, not in a vacuum, but in light of the disclosure, prior art, and ordinary skill in the pertinent art. Given the above standard, Applicants respectfully submit that the claims are definite.

Applicants respectfully submit that the Examiner has impermissibly separated terms "improving decreased bone mass" and "improvement of decreased bone mass" into two separate pieces. *Office Action* at page 12. In doing so, the Examiner has interpreted "improving decreased bone mass" and "improvement of decreased bone mass" as "improving," "improvement," and "decreased bone mass." *Id.* This interpretation is improper because it ignores the specification and interprets the claims in a vacuum. Thus, concerning the claimed invention, the definiteness standard under 35 U.S.C. § 112, second paragraph, should be determined with respect to the terms "improving decreased bone mass" and "improvement of decreased bone mass."

The definiteness of the claimed invention is further confirmed by the context of the specification. The specification describes the OCIF protein as being useful as a pharmaceutical ingredient for treating decreased bone mass in disorders such as osteoporosis, rheumatism, osteoarthritis, and abnormal bone metabolism in multiple myeloma. Specification at column 10, lines 18-20. Since one of skill in the art would readily recognize that osteoporosis is a disease in which bone density is decreased relative to a non-diseased state, a method of "improving" decreased bone density would be understood as maintaining bone mass, increasing bone mass, or reducing decrease of bone mass. In this context, Applicants respectfully submit that the terms "improving decreased bone mass" and "improvement of decreased bone mass" are clearly definite.

Figure 15 of the specification also confirms the definiteness of the term "improving" or "improvement." Specification at page 10, lines 12-17 and Figure 15. In this figure, the administration of OCIF to denerved rats increased the mechanical strength of bone in a dose dependent manner. *Id.* Viewed in this context, Applicants submit that "improving" or "improvement" refers to an increase of bone mass or some other physical property relative to an untreated state. This is sufficient to satisfy the definiteness requirement under 35 U.S.C. 112, second paragraph.

In light of the above, Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

IV. Nonstatutory Double Patenting Rejection

The Examiner asserts that claims 32-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 32, 33, 35, and 36 of co-pending Application No. 10/979,654. *Office Action* at page 14. In rejecting these claims, the Examiner asserts that the conflicting claims are "not patentably distinct from each other because both sets of claims are directed to administration of an OCIF polypeptide." *Id.* Applicants respectfully disagree.

Applicants respectfully submit that the Examiner has provided no evidence that claims 32-37 are obvious in view of claims 32, 33, 35, and 36 of co-pending Application No. 10/979,654. However, in order to facilitate prosecution, Applicants are willing to consider submitting a Terminal Disclaimer in the present case with regard to U.S. Application Serial No. 10/979,654 upon an indication of allowable subject matter. Additionally, it is noted that the filing of a terminal disclaimer to obviate a rejection based on non-statutory double patenting is not an admission of the propriety of the rejection. *See, e.g., Quad Environmental Technologies Corp. v. Union Sanitary Distric*t, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991) ("filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection"). In light of the above, Applicants respectfully request that the Examiner hold in abeyance the nonstatutory double patenting rejections over claims 32, 33, 35, and 36 of co-pending Application No. 10/979,654.

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding objection and rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5186 should any additional information be necessary for allowance.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408)
Kristan L. Lansbery (Reg. No. 53,183)

Date: October 27, 2006

ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
(202) 942-5000 telephone
(202) 942-5999 facsimile